

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,

Case No. 0:08-CV-1658 (PJS/RLE)

Plaintiff,

v.

ORDER FOR INJUNCTION AND
ENTRY OF JUDGMENT

CAPTAIN'S SELECT SEAFOOD, INC., a
corporation, and CAROLYN M. YOUNG
and WILLIAM J. YOUNG, individuals,

Defendants.

Gerald C. Kell, UNITED STATES DEPARTMENT OF JUSTICE, for plaintiff.

Thomas P. Kane, Steven H. Sifton, and Mark T. Berhow, HINSHAW & CULBERTSON
LLP, for defendants.

This matter is before the Court on the government's motion for summary judgment and entry of a permanent injunction. Also pending are two motions of defendants. Each of defendants' motions takes the form of a motion seeking an enlargement of time to respond to the government's summary-judgment motion. In fact, though, defendants' papers address the government's motion on the merits, and include a number of exhibits submitted in opposition to the government's motion. For the reasons that follow, the Court grants defendants' motions for enlargement of time, but also grants summary judgment to the government.

I. BACKGROUND¹

Defendants Carolyn and William Young owned and operated defendant Captain's Select Seafood, Inc. ("Captain's") for about thirteen years, until they closed Captain's in August 2008.² Young Aff. (First) at ¶¶ 14, 16 [Docket No. 22]. While it was in operation, Captain's supplied seafood to many high-end restaurants in the Twin Cities. Young Aff. Resp. Becoat Decl. Ex. A.³

As a seafood processor, Captain's was required to comply with regulations promulgated by the United States Food and Drug Administration ("FDA"). In particular, Captain's had to adopt what is known as a "Hazard Analysis and Critical Control Point" or "HACCP" plan.⁴ See 21 C.F.R. part 123. FDA regulations provide that seafood prepared in the absence of a proper HACCP plan is deemed "adulterated" for purposes of 21 U.S.C. § 342(a)(4). 21 C.F.R.

¹The facts are undisputed, except as indicated in the text.

²For ease of exposition, the Court generally refers to defendants collectively as "Captain's."

³The Young affidavit responding to the Becoat declaration was filed as Exhibit B to one of defendants' motions for enlargement of time [Docket No. 42]. That affidavit has additional exhibits that are also designated by letters. For example, copies of letters from restaurants that did business with Captain's are Exhibit A to the Young affidavit — which, as noted, is itself Exhibit B to one of defendants' motions.

The Court suggests that if a party files exhibits that themselves have exhibits, the two types of exhibits should use different labeling schemes. For instance, primary exhibits might be labeled "A" and "B," and exhibits to those primary exhibits might be labeled "A-1" and "B-1." In this case, Exhibit A to one of defendants' motions for enlargement of time is the affidavit of William Spinali; Exhibit A to that affidavit is a letter from the FDA; and these two Exhibits A must be distinguished from Exhibit A to the Young affidavit (itself exhibit B to the motion), just as Exhibit B to the motion (the Young affidavit) must be distinguished from Exhibit B to the Spinali affidavit (itself Exhibit A to the motion). It is hard to keep these exhibits straight, and even harder to cite them concisely and coherently.

⁴The acronym HACCP is pronounced "*hass-əp*" or "*hass-ip*."

§ 123.6(g). And under 21 U.S.C. § 331(k), causing food to become adulterated is unlawful. 21 U.S.C. § 331(k).

Representatives of the FDA inspected Captain's four times between April 2004 and July 2007. Becoat Decl. ¶¶ 10-11 [Docket No. 14 Ex. 2]. The FDA concluded, after each inspection, that Captain's did not have an adequate HACCP plan. *Id.* ¶¶ 11, 19. After the most recent inspection, in July 2007, the FDA issued a form detailing Captain's regulatory violations, and the FDA inspector discussed those violations with Carolyn Young, who promised to correct them. *Id.* ¶ 18 & Ex. 2(B).

Captain's submitted revised HACCP plans to the FDA in April and May of 2008. *Id.* ¶ 24; Samuels Decl. [Docket No. 14 Ex. 1] Exs. 1(B), 1(C), 1(D). On May 30, 2008, the FDA wrote a letter to Captain's identifying numerous alleged deficiencies in the May 2008 HACCP plan. Samuels Decl. Ex. 2(J). Captain's submitted yet another revised plan on June 1, 2008. *Id.* Ex. 1(D).

The FDA found the June 1, 2008 plan unsatisfactory and filed this suit on June 6, 2008. The FDA seeks to enjoin Captain's from operating until it adopts an acceptable HACCP plan and passes FDA inspections. The FDA's proposed injunction would also limit the ability of Carolyn and William Young to work in the food-service industry.

II. DISCUSSION

A. Standard of Review

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute over

a fact is “material” only if its resolution might affect the outcome of the suit under the governing substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute over a fact is “genuine” only if the evidence is such that a reasonable jury could return a verdict for either party. *Ohio Cas. Ins. Co. v. Union Pac. R.R.*, 469 F.3d 1158, 1162 (8th Cir. 2006). In considering a motion for summary judgment, a court “must view the evidence and the inferences that may be reasonably drawn from the evidence in the light most favorable to the non-moving party.” *Winthrop Res. Corp. v. Eaton Hydraulics, Inc.*, 361 F.3d 465, 468 (8th Cir. 2004).

B. Basis for Injunction

According to the FDA, Captain’s long history of having inadequate HACCP plans establishes that Captain’s violated 21 U.S.C. § 331(k) by selling adulterated seafood. The FDA seeks an injunction forbidding Captain’s and the Youngs from operating any food-related business until the FDA has approved a HACCP plan developed for them by an independent expert and the FDA has given them permission to resume operations. Proposed Order ¶ IV.

In opposing the FDA’s motion for summary judgment, Captain’s argues primarily that the June 1, 2008 HACCP plan complies with FDA regulations. Captain’s relies mainly on the testimony of its consultant, William Spinali, who worked with Captain’s to revise its HACCP plans and to respond to the May 30, 2008 letter from the FDA identifying deficiencies. Spinali Aff. [Docket No. 23]. In his own letter dated May 30, 2008, Spinali took issue with the ostensible deficiencies identified in the FDA’s May 30 letter. *Id.* Ex. B. And in his affidavit dated June 5, 2008, Spinali asserted that “Captain’s current HACCP Plans are in full compliance with all FDA regulations.” Spinali Aff. ¶ 6.

If summary judgment turned on whether the HACCP plan proposed by Captain's on June 1, 2008 complied with FDA regulations, the Court would be unable to grant summary judgment. On the one hand, Spinali — who appears to be a qualified food-safety expert — says that the June 1, 2008 HACCP plan complies with FDA regulations. On the other hand, Robert Samuels, an FDA employee who works in the area of seafood safety, disagrees. Samuels Decl. ¶¶ 26-33. The Court would require additional evidence to resolve this disagreement among experts.

But for purposes of this case, the Court need not decide whether the June 1, 2008 HACCP plan complies with FDA regulations. Captain's does not dispute the FDA's assertion that from 2004 through at least early 2008, Captain's did not have a HACCP plan that complied with FDA regulations. This lengthy and undisputed history is sufficient to establish that Captain's violated 21 U.S.C. § 331(k) on countless occasions by handling food in a manner that rendered that food "adulterated."⁵

Section 332(a) of Title 21 of the United States Code empowers district courts to enjoin violations of § 331. 21 U.S.C. § 332(a). Accordingly, because the government has established that Captain's violated § 331(k), the government is entitled to an injunction if it also establishes a cognizable danger of recurrent violations. *See United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 28 (2d Cir. 1972) ("The passage of the [Food, Drug, and Cosmetic Act] is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained."); *United States v. SeneX Eleemosynary Corp.*, 479 F. Supp. 970, 980-81 (S.D. Fla. 1979). Given

⁵Again, to be clear, this means merely that Captain's handled food at a time when it did not have an adequate HACCP plan. It does not mean that anything was wrong with the food that Captain's was supplying to its customers.

the lengthy history of admitted violations by Captain's, the Court finds that the government has established a likelihood of additional violations if Captain's resumes operations as a seafood processor or if the Youngs resume work as seafood suppliers.

The injunction sought by the government, however, is overly broad in light of the conduct of Captain's and the Youngs. In particular, the government's proposed injunction would forbid the Youngs to "prepare, pack, hold, or distribute[] any food" unless they come up with a HACCP plan approved by the government. Proposed Order ¶ IV. This would seem to prevent the Youngs from working in the food industry in any capacity. But the history of Captain's violations does not suggest that the Youngs are incapable of acting as, for instance, food servers at someone else's restaurant.

Further, the government's proposed injunction gives the FDA almost total discretion over whether to approve a HACCP plan proposed by Captain's. The Court believes that, under the circumstances of this case, Captain's should have the ability to seek judicial review of the FDA's decision with respect to a proposed HACCP plan. The Court has fashioned its injunction accordingly.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. The government's motion for summary judgment [Docket No. 11] is GRANTED.
2. Defendants' motions for enlargement of time to respond to the government's motion through October 27, 2008 [Docket Nos. 42 and 43] are GRANTED.

3. Defendants Captain's Select Seafood, Inc., Carolyn M. Young, and William J. Young are ENJOINED from violating 21 U.S.C. § 331(a) and (k) as follows:
 - a. Defendants must not introduce or deliver for introduction into interstate commerce any food that is adulterated under 21 U.S.C. § 342(a)(4).
 - b. Defendants must not do anything to cause food being held for sale after shipment in interstate commerce to become adulterated under 21 U.S.C. § 342(a)(4).
4. Defendants Captain's Select Seafood, Inc., Carolyn M. Young, and William J. Young are ENJOINED from operating, either directly or indirectly, Captain's Select Seafood, Inc., any food-supply business, or any food-related business involving seafood, unless either the FDA or a federal district court approves the business's HACCP plan in accordance with the following procedures:
 - a. Before operating, either directly or indirectly, Captain's Select Seafood, Inc., any food-supply business, or any food-related business involving seafood, defendants must give the FDA 90 days notice of their intention to operate such a business and must provide the FDA with a copy of the HACCP plan under which they propose to operate.
 - b. If the FDA approves the HACCP plan, defendants may operate the proposed business covered by the plan.
 - c. If the FDA does not approve the HACCP plan, and if the FDA wishes to prevent defendants from beginning to operate the proposed business covered by the plan, the FDA must bring an enforcement action in federal

district court within 90 days of receipt of the plan to enjoin defendants from operating the proposed business.

- d. If the FDA brings such an enforcement action, defendants will not be permitted to operate, directly or indirectly, the proposed business unless they prevail in the enforcement proceeding. Defendants will not be permitted to operate, directly or indirectly, the proposed business during the pendency of the enforcement action unless the court in which the action is pending orders otherwise.
5. Defendants Captain's Select Seafood, Inc., Carolyn M. Young, and William J. Young must provide a copy of this order within 15 days of the date of this order by personal service or by certified mail, return receipt requested, to all of defendants' officers, agents, servants, employees, and attorneys, and to all other persons who are in active concert or participation with defendants or with their officers, agents, servants, employees, and attorneys.
6. Defendants must provide the Director of the FDA Minnesota District Office and the government's attorney, within 20 days of the date of this order, an affidavit based on personal knowledge identifying all persons, and the positions of those persons, who received copies of this order pursuant to the preceding paragraph, and stating for each person whether the order was provided personally or by mail.
7. All communications with the FDA required by this order must be provided to:

Director
FDA Minnesota District Office
250 Marquette Ave., Suite 600

Minneapolis, MN 55401

8. Defendants must post a copy of this order in the employee common areas of any food-processing facility currently owned, leased, or operated, directly or indirectly, by any of the defendants.
9. Defendants must provide a copy of this order to any new employee hired by Captain's Select Seafood, Inc., within 15 days of that person's hiring date.
10. Defendants must notify the FDA in writing at least 20 days in advance of:
 - a. any change in the ownership or character of Captain's Select Seafood, Inc., such as dissolution, assignment, bankruptcy, sale of the company, creation or dissolution of subsidiaries, or any other change in the company's corporate structure; or
 - b. the sale or assignment of any business assets, such as buildings, equipment, or inventory, if that sale or assignment may affect compliance with this order.
11. At least 15 days before making any assignment or transferring any interest in Captain's Select Seafood, Inc., or its assets as described in the preceding paragraph, defendants must provide a copy of this order to any proposed successor or assignee. Defendants must provide the FDA with an affidavit based on personal knowledge stating how and when defendants complied with the notice provision in this paragraph.
12. In accordance with Rule 65(d)(2) of the Federal Rules of Civil Procedure, this order binds not only defendants, but also the following who receive actual notice

of it: defendants' officers, agents, servants, employees, and attorneys; and other persons who are in active concert or participation with defendants or with their officers, agents, servants, employees, and attorneys.

13. This order does not in any way limit the FDA's ability under generally applicable federal laws and regulations to regulate, monitor, inspect, and supervise Captain's Select Seafood, Inc., or any business operated, directly or indirectly, by Carolyn M. Young or William J. Young. This order also does not in any way relieve Captain's Select Seafood, Inc., Carolyn M. Young, or William J. Young of their obligations to comply with generally applicable federal laws and regulations.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: February 17, 2009

s/Patrick J. Schiltz

Patrick J. Schiltz

United States District Judge